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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,833	09/26/2000	Linda S. Mansfield	MSU 4.1-528	2531
21036 7590 08/08/2007 MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864			EXAMINER BASKAR, PADMAVATHI	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 08/08/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/669,833	Applicant(s) MANSFIELD ET AL.	
	Examiner Padmavathi v. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment

1. Applicant's amendment filed on 5/11/07 is acknowledged and entered.

Status of claims

2. Claim 29 has been amended.
Claims 1-28 and 30-50 have been cancelled.
New claims 51 and 52 have been added.
Claims 29, 51 and 52 are pending in the application.

Claim Rejections 35 USC 112, second paragraph withdrawn

3. In view of amendment to the claim, the rejection under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 112, first paragraph maintained

4. The written description rejection of claim 29 remains rejected and newly added 51-52 are also rejected under 35 U.S.C. 112, first paragraph is maintained set forth in the previous office action.

Applicant states that possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

Applicant's arguments have been fully considered but found to be non-persuasive because the invention cannot be complete in the absence of a written description of the antigen used for producing passive immunity and for the reasons of record, the specification provides no information drawn to the structure of the antigens such that they could be predictably distinguished from other antigens within the range of molecular weights claimed. For this reason, the claimed invention is not ready for patenting, none of drawings nor structural formulas no sequences of the claimed antigens are disclosed.. Further, Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed. " Enzo Biochem, 323 F.3d at 963, 63 USPQ2d at 1613 . In this case applicants specification provides *S. neurona* merozoites antigens 16 kDa antigen and/or 30 kDa antigen and making polyclonal antibodies by methods known to the art. However, the claims are drawn to passive immunity vaccine and the specification fails to describe any specific antigen within the claimed range of 12 - 20 kD or 26-34 kD that is useful for producing antibodies that will provide passive immunity vaccine to horses against *Sarcocystis neurona*. Further, applicant failed to provide fact based evidence to support that applicant is in possession of passive immunity vaccine.

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Applicant states that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case'.

Applicant's arguments have been fully considered but found to be non-persuasive because the specification does not provide an adequate written description in the context of the claims.

5. The enablement rejection claim 29 remains rejected and newly added 51-52 are also rejected under 35 U.S.C. 112, first paragraph is maintained as set forth in the previous office action.

Applicant states that the lack of working examples should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.

Applicant's arguments have been fully considered but found to be non-persuasive because the rejection of record does not solely depend on lack of working example but also based on other factors such as undue experimentation since the claim is drawn to a whole multitude of antigens within 12-20 kD and 26-34 kD and it cannot be predicted from the information in the specification which of the whole multitude of antigens will be useful to produce a passive immunity vaccine against *S. neurona*.

Claim Rejections - 35 USC 103 maintained

6. The rejection of claims 29 and 51-52 under 35 U.S.C. 103(a) as being unpatentable over Liang et al 1998 (Infection and Immunity; 66 (5) 1834-1838 in view of Harlow and Lane 1988 (Antibodies; Cold Spring Harbor).

Applicant states that the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination and that the references must be viewed without the benefit of hindsight reasoning.

Applicant's arguments have been fully considered but found to be non-persuasive because the examiner established the obviousness based on the evidence from Liang et al's teachings. Briefly Liang teaches EPM disease occurs only after the merozoite passes through the vascular endothelium of the blood-brain barrier (see discussion in Liang et al 1998) into the central nervous system and is found in the CSF. Liang also teaches that although many horses are found to test positive for the panel of antibodies, only a subset of those that test positive are actually found to have (see page 1834, 3rd para) EPM because the antibodies indicate not only disease but also exposure to infection. Further Liang et al identifies that antisera to the 30kD are also consistently found in horses with neurologic signs typical of EPM and specific antibodies to 30kD antigen are important in order to diagnose EPM and to distinguish EPM caused by *S. neurona* infection. This is not a hindsight reasoning as applicant puts forth.

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Applicant states that the cited prior art references do not teach or suggest all of the limitations of the claimed method.

Applicant's arguments have been fully considered but found to be non-persuasive because the rejection of record correctly established the obviousness including teaching, suggestion, motivation although the recent Supreme Court *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350, slip op. at 14, 15 (U.S. April 30, 2007) decision indicates that teaching, suggestion, motivation (TSM) test is not a rigid and mandatory formula. However, the examiner used the Liang et al's teachings as one of the valid rationale to establish the obviousness because Liang et al recognized the problem of cross reactive antibodies with other *Sarcocystis* infections and the need in the art to solve the problem by making specific antibodies to *Sarcocystis* *neurona*. Therefore, one of ordinary skill in the art could have pursued to make the antibodies with a reasonable expectation of success to solve the art recognized problem as discussed in the rejection of record.

Remarks

7. No claims are allowed.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787.



Padma Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

